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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/673,895	09/29/2003	Spencer Erich Hochstetler	80043-01	1979

40850 7590 01/24/2008

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EXAMINER	
AFREMOVA, VERA	

ART UNIT	PAPER NUMBER
1657	

NOTIFICATION DATE	DELIVERY MODE
01/24/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/673,895	HOCHSTETLER ET AL.	
	Examiner	Art Unit	
	Vera Afremova	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6,7 and 9-40* is/are pending in the application.

4a) Of the above claim(s) *18-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6,7 and 9-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-4, 6, 7 and 9-17 as amended (11/02/2007) are under examination in the instant office action.

This application contains claims 18-40, drawn to invention(S) nonelected with traverse in the reply filed on 4/22/2007. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6, 7, and 9-11 as amended remain/are rejected under 35 U.S.C. 102(b) as being anticipated by DE 196 25 137 as explained in the prior office action.

Claims are directed to a method for disrupting living cells as intended for ATP release from the living cells wherein the method comprises one active step of agitating an aqueous mixture of 1) polymer or pigment in the presence of 2) a particulate disruption agent to cause rupture of the cells. Some claims are further drawn to the living cells being fungal or bacterial cells including *Candida sp.* and *Burkholderia cepacia.* Some claims are further drawn to the presence of a generic organic pigment during agitating step. Some claims are further drawn to the presence of polymers including polyether, acrylic polymer and/or polyesters during agitating

step. Some claims are further drawn to the presence of a generic cosmetic, coating or adhesive material during agitating step. Some claims are further drawn to the presence of a generic plastic disrupting oval agent during agitating step.

DE 196 25 137 discloses a method for disrupting living cells as intended for ATP release from the living cells (see page 6, for example) wherein the method comprises active step of agitating an aqueous mixture comprising living cells and 1) acrylic polymer or a generic organic pigment and 2) a disrupting agent that is either a lysis reagent as taught by reference or a styrene polymer within the meaning of the instant claims drawn to a plastic disruption agent (claim 10). The disclosed polystyrene is in a form of dispersion and, thus, it is large enough to be considered a particulate agent having amorphous or oval shape within the meaning of the instant claims. The living cells include *Candida sp.*, *Escherichia sp.* and *Burkholderia cepacia* (page 9).

Thus, the cited patent teaches all structural elements in the method for releasing ATP from living cells as required for the claimed method. Thus, the cited reference anticipates the claimed invention.

Claims 1-3 as amended remain/are rejected under 35 U.S.C. 102(b) as being anticipated by EP 542 790 as explained in the prior office action.

Claims are directed to a method for disrupting living cells as intended for ATP release from the living cells wherein the method comprises one active step of agitating an aqueous mixture of 1) polymer or pigment in the presence of 2) a particulate disruption agent to cause cell rupture. Some claims are further drawn to the living cells being fungal or bacterial cells

including *Serratia sp.* Some claims are further drawn to the use of a generic organic pigment, to the use of a generic polyether polymer, to the use of a generic plastic disrupting round agent.

EP 542 790 discloses a method for disrupting living cells as intended for ATP release from the living cells (page 9, examples) wherein the method comprises one active step of agitating an aqueous mixture of 1) polymer in the presence of 2) a particulate disruption agent to cause cell rupture. The polymer is Triton X-100 and the particulate disruption agent is polystyrene beads (page 10, lines 1-4). The living cells belong to *Serratia sp.* (page 9, line 17).

Thus, the cited patent teaches all structural elements in the method for releasing ATP from living cells as required for the claimed method. Thus, the cited reference anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 6, 7 and 9-17 as amended remain/are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 542 790 and Calvo-Bado et al. (Applied and Environmental Microbiology. April 2003, Vol. 69, pages 2116-2125) and DE 196 25 137 taken with Geciova et al ("Methods for disruption of microbial cells for potential use of the dairy industry". International Dairy Journal. 2002, 12: 541-553) and US 5,017,564 as explained in the prior office action and for the reasons below.

Claims are directed to a method for disrupting living cells as intended for ATP release from the living cells wherein the method comprises one active step of agitating an aqueous mixture of 1) polymer or pigment in the presence of 2) a particulate disruption agent to cause rupture of the cells. Some claims are further drawn to the living cells being fungal or bacterial cells including *Candida sp.*, *Serratia sp.*, *Burkholderia cepacia, Bacillus subtilis, Pseudomonas, etc.* Some claims are further drawn to the presence of a generic pigment including organic polymer, inorganic pigments, sand, etc. during agitating step. Some claims are further drawn to the presence of polymers including polyether, acrylic polymer and/or polyesters during agitating step. Some claims are further drawn to the presence of a generic cosmetic, coating or adhesive material during agitating step. Some claims are further drawn to the use of the disrupting agent made from plastic or glass, having bead shape, having diameter 0.1-1 mm. Some claims are further drawn to agitating on a bead mill with 100-10,000 oscillations per minute for 0.1-5 minutes.

The cited references EP 542 790, Calvo-Bado et al. and DE 196 25 137 teach methods for disrupting living cells as intended for ATP release from the living cells. The methods of EP 542 790 and DE 196 25 137 comprise step of agitating sample suspected in contamination with biological cells in an aqueous dispersion of both polymers and particulate agents in order to cause rupture of the cells and release of intracellular ATP as explained above. The method of Calvo-Bado et al comprise step of agitating an environmental sample contaminated with cells in the presence of a particulate disruption agent or with 0.1 mm glass beads to cause rupture of the cells and release of ATP (entire document including section "ATP extraction" on page 2118).

The cited references EP 542 790, Calvo-Bado et al. and DE 196 25 137 teach release of ATP and disruption of various microbial cells including *Candida sp., Serratia sp., Burkholderia cepacia, Bacillus subtilis, Pseudomonas, etc.* The disruption agents include plastic beads (EP 542 790), particulate plastic materials (DE 196 25 137) and glass beads (Calvo-Bado et al. page 2118, col. 1, par. 5). The aqueous mixtures of polymers taught by EP 542 790 and DE 196 25 137 include dispersions of acrylic polymers, polyesters, polyethers, polystyrenes. The cited reference by Calvo-Bado et al. also teaches the use of 0.1 mm size of beads for disruption of microbial cells as intended for ATP release and the use of BioSpect bead mill for agitation of cells with beads for about 5 minutes (page 2118, col. 1, par. 5).

Thus, the cited references EP 542 790, Calvo-Bado et al. and DE 196 25 137 as a whole teach and suggest all structural elements in the method for disrupting living cells with beads in polymer/pigment dispersions as intended for ATP release from the living cells. Although the cited reference by Calvo-Bado et al. does not explicitly teach the use of polymeric surfactants in the methods for disrupting biological cells and releasing intracellular materials, the other cited references EP 542 790 and DE 196 25 137demonstrate that polymeric surfactants are used in the methods for cell disruption and separation of intracellular materials and cell debris.

The following references are additionally relied upon to demonstrates that bead size and milling time and/or speed (oscillation per minute) during disruption is commonly modified depending on type of living cells present or suspected in the samples (Geciova et al. at page 544, col. 1) and that unstable ATP could be protected in the presence of coating materials including acrylic copolymers, cellulosic polymers, colorants (US 5,017,564 at col. 6, lines 40-55).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to use particulate disrupting agents including glass beads for disrupting living cells in dispersions with polymers and/or pigments with a reasonable expectation of success in releasing ATP as intended for detection of living cells as adequately taught and/or suggested by the cited references EP 542 790, Calvo-Bado et al. and DE 196 25 137. Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary. One of skill in the art would have been motivated to modify bead size and agitation speed with regard to the type of living cells as adequately taught and/or suggested by Geciova et al. One of skill in the art would have been motivated to use polymers and/or colorants to stabilize ATP released from the disrupted living cells as adequately taught and/or suggested by US 5,017,564 for the expected benefits in stabilizing ATP for consecutive measurement and maximizing ATP amount correlation with the quantity of cells present in the analyzed samples.

The claimed subject matter fails to patentably distinguish over the state art as represented be the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

Response to Arguments

Applicant's arguments filed 11/02/2007 have been fully considered but they are not all found persuasive.

With regard to the claim rejection under 35 U.S.C. 102(b) as being anticipated by DE 196 25 137 Applicants argue that the method of the cited reference does not encompass the use of "a particulate disrupting agent" as claimed because polymers usually form particles of such small

sizes that might be ineffective for cell rupture. Yet, the claims are not limited to the size of disrupting particles as intended. Although claims are read in the light of specification, the specification limitations are not read into the claims. The teaching of the reference by Geciova et al, that is argued by Applicants as what one of skill in the art would consider as "disrupting" particle, relates to the use of a specific apparatus such as a bead mill. The use of a bead mill is not recited in the rejected claims. The polymeric surfactants are known to interact and to disrupt cell membranes and, thus, they are "disrupting" agents within the broadest meaning of the claims.

With regard to the claim rejection under 35 U.S.C. 102(b) as being anticipated by EP 542 790 Applicants argue that the method of the cited reference does not encompass the use "an aqueous dispersion or emulsion of a polymer" as claimed because Triton X-100 is soluble in water and, therefore, would not provide for 2 phase aqueous dispersion or emulsion. This argument is not found particularly convincing because Triton X-100 has both hydrophilic and hydrophobic groups such as polyethylene oxide hydrophilic group and hydrocarbon lipophilic or hydrophobic group, and, thus, it is capable to divide or to separate 2 phases in a solution with water soluble and water insoluble components. Applicants further argues that the polysterene beads used in the cited methods are too small to rupture the cells in view of teaching of the reference by Geciova et al. However, Geciova et al. teaches the size of particles in a different apparatus or in a bead mill. The use of a bead mill is not recited in the rejected claims.

Claim rejection under 35 U.S.C. 102(a) as being anticipated by Calvo-Bado et al. has been withdrawn because the method of the cited reference does not comprise the use of "an aqueous dispersion or emulsion of a polymer or organic pigment".

With regard to the claim rejection under 35 USC § 103 Applicants argue that there is no suggestion to combine references. However, the cited references EP 542 790, Calvo-Bado et al. and DE 196 25 137 are in the same field of endeavor (such as disruption of cells in aqueous dispersions with polymers and/or particulate materials) and they seek to solve the same problems as the instant application and claims (such as disruption of cells as intended for ATP release and measurement), and one of skill in the art is free to select components available in the prior art, *In re* Winslow, 151 USPQ 48 (CCPA, 1966).

With regard to the reference by Geciova et al. Applicants appear to argue that the reference teaching is generic. Nevertheless, the reference clearly discloses various methods for cell disruption including mechanical (bead mill) and non-mechanical (detergents or surfactants) methods (entire document including fig. 1).

Further, with regard to US 5,017,564 (Makino et al) Applicants argue that this reference has no meaningful relationship with other cited references since it has nothing to do with cell disruption and detection of ATP in cell debris. US 5,017,564 is relied upon for the teaching that cell unbound and unstable ATP could be protected in the presence of acrylic polymers (see claim 7, for example) and that acrylic polymers are usually used in the coating materials. At least some of the claims (claim 9) recite the presence of "coating", " adhesive" and/or "cosmetic" components in the "aqueous dispersion or emulsion" wherein cells are disrupted as intended for release and detection of ATP. Moreover, the claimed "polymer or organic pigment" has no specific function for release and detection of ATP as intended by applicants. The method of the instant application and claims is intended for detection of biological contamination in manufactured polymers, paints, coatings by mechanical disruption of cells and detection of

intracellular component such as ATP (specification page 1 par. 0001-0002 and page 24, table 2). The table 1 (specification page 1) discloses results of ATP release by mechanical means only (bead mill) in the industrial contaminated polymeric products or in latex dispersion with simulated contaminations.

Thus, the claimed subject matter fails to patentably distinguish over the state art as represented be the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber, can be reached at (571) 272-0925.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

AU 1657

January 17, 2008

V. Afremova

VERA AFREMOVA

PRIMARY EXAMINER